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Date: Dec 5, 2018
To: Whom it may concern

Document Number: DN0007169
Revision: AC

From: OSTA, Gyrus ACMI, an Olympus company. (Formerly Gyrus ENT LLC, and Smith & Nephew, Inc., ENT Division)

MRI Information for Gyrus ACMI Otology Implant Devices

Magnetic resonance imaging (MRI) may be contraindicated for patients with a metallic implant because of risks associated with movement or dislodgment for ferromagnetic implants and MRI-related heating for metallic or conductive implants that are a certain length or that form a closed conducting loop. With the exception of several old production lots of a particular type of middle ear (i.e., otologic or ossicular) implant (see Table 1) manufactured and distributed in late 1987 and early 1988, materials used by Gyrus ACMI in the manufacturing of middle ear implants are generally considered acceptable for patients undergoing MRI procedures (see below).

Table 1.

Specific Lots of S&N, Inc. (Richards) McGee Platinum/Stainless Steel Pistons Contraindicated for MRI

This series of McGee Platinum/Stainless Steel Pistons were manufactured using a ferromagnetic stainless steel in late 1987 and early 1988. The affected production lots of these pistons, given in Table 1 below, were recalled by Smith & Nephew, Inc. in 1989. Importantly, MRI is contraindicated for anyone implanted with a McGee Platinum/Stainless Steel Piston from these lots.

S&N Catalog No.	Lot Nos.
14-0330	1W91100, 4U09690
14-0331	4U09700
14-0332	1W91110, 4U58540, 4U86300
14-0333	4U09710, 1W91120
14-0334	4U09720, 1W34390, 2WR4073
14-0335	1W34400, 4U09730

S&N Catalog No.	Lot Nos.
14-0336	3U18350, 3U50470, 4UR2889
14-0337	3U18370, 4UR2889
14-0338	3U18390, 4U02900, 4UR1453
14-0339	3U18400, 3U50480
14-0340	3U18410, 3U50500
14-0341	3U41200, 4UR2889

MRI Safety Information

All current Gyrus ACMI MR Conditional permanent implants are packaged with an MRI Identification Patient Card. Please review the explanation of the previous and current labeling terms applied to implants and devices, as follows:

MR Safe*

Devices that are made from non-metallic materials (i.e., implants and ventilation tubes made from Hydroxylapatite (HA), Plasti-pore, Silicone, Fluoroplastic) are inherently non-conducting and non-magnetic and pose no known hazards in all MR environments and, therefore, are MR Safe. See Table 2.

MR Conditional*

Devices that have been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Conditions that define the MRI environment may include the static magnetic field strength, the spatial gradient magnetic field, time-varying magnetic fields, radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system) or other may be required to ensure patient safety

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The **MR Conditional Information** for Gyrus ACMI implants (excluding the Lots listed in Table 1 above) is, as follows:

Non-clinical testing of representative worst case samples has demonstrated that patients with these specific Gyrus ACMI otologic implants can be safely scanned in an MR system, immediately after implantation, meeting the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- For items in Table 3: Maximum spatial gradient magnetic field of 1,000-Gauss/cm or less.
- For items in Table 4: Maximum spatial gradient magnetic field of 4,000-Gauss/cm or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

MR Related Heating
Under the scan conditions defined, the implants are expected to produce a maximum temperature rise of 1.5° C after 15-minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information
In non-clinical testing, the image artifact extends approximately 5 to 25 mm from the implant, depending on size and implant, when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

The following tables summarize the Gyrus ACMI implants, based on worst case representative sample testing (data on file), available literature reviewed as referenced below [1-8], and a review of the materials used in their construction as allowed by ASTM F2503[9].

Table 2. MR Safe (materials include Hydroxylapatite (HA), Fluoroplastic, Plasti-pore, Hapex, Silicone, and Polyethylene)

Device Family	**Family Product Number(s)**	**Device Family**	**Family Product Number(s)**
Grate / Grote Canal, HA Reconstruction Blocks, Attic Defect, Wehrs Incus, Kartush, FLPL Pistons, PORP	1408XX, 709217XX, 7014XXX, 1409XX, 1404XX, 1405XX, 1400XX	Applebaum Incus Replacement	1409XX
Vocom	1430XX, 70143019	Austin Mod TORP, PORP	140063, 140057
HA Granules	911101	Black Oval, TORP/PORP	1408XX, 1409XX
Jahn Tube	1409XX	Non-metallic Ventilation Tubes	Multiple

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Table 3. MR Conditional (materials include Nitinol, nonmagnetic Stainless Steel, Titanium, Tantalum, and Platinum)

Device Family	Family Product Numbers(s)	Device Family	Family Product Numbers(s)
CAP / TORP / PORP	1408XX, 701458XX, 701405XX, 70143XXX, 70145XXX, 1400XX, 140XXX, 70140XXX, 70141XXX	Metallic Vent Tubes	1452XX-ENT, 145701, 70145XXX, 1452XX
Micron, Micron II	70142XXX, 70141XXX	Kartush Incus	1408XX, 70145XXX
Smart Pistons	70142XXX, 70143XXX, 70145XXX	Ribbon loops	1407XX
Pistons (various)	141XXX, 140XXX, 70140XXX, 70145XXX, 1407XX	Black Oval TORP	140858, 140861, 140894, 140897
Bucket Handles, Cups, Classic	70142XXX, 142XXX, 1404XX, 1406XX, 70921XXX	Wehrs Incus	701458XX, 701409XX, 140XXX
Goldenberg	1409XX, 701459XX		

Table 4. MR Conditional (extra small implants: materials include nonmagnetic Stainless Steel, and Tantalum)

Device Family	Family Product Numbers(s)	Device Family	Family Product Numbers(s)
House Type wire Loops	1401XX, 14072X	Sheehy-Type Incus Strut	1404XX

(XX = 00 through 99) (XXX = 000 through 999)

1. Fritsch MH, Gutt JJ, and Naumann IC. Magnetic Properties of Middle Ear and Stapes Implants in a 9.4-T Magnetic Resonance Field. Otology & Neurotology 2006; 27: 1064-1069.
2. Applebaum EL, Valvassori GE. Effects of magnetic resonance imaging fields on stapedectomy prostheses. *Archives of Otolaryngology* 1985; 111:820-821.
3. Hirsch BE, Weissman JL, Curtin HD, and Kamerer DB. Imaging of ossicular prostheses. *Otolaryngology – Head and Neck Surgery* 1994; 111:494-496.
4. Rodriquez P. MRI indication for the referring surgeon. http://www.gcnet.com/maven/aurora/mri/precatuions.html.
5. Shellock FG. MR imaging of metallic implants and materials: A compilation of the literature. *AJR* 1988; 141:811-814.
6. Shellock FG. Implants and Device: Labeling for MRI and an explanation of Terminology. MRIsafety.com
7. White DW. Interaction between magnetic fields and metallic ossicular prosthesis. *American Journal of Otolaryngology* 1987; 8(2):90-92.
8. Azadarmaki R, Tubbs R, Chen DA, Shellock FG. MRI information for commonly used otologic implants: review and update. Otolaryngol Head Neck Surg. 2014;150:512-9.
9. ASTM F2503-13: American Society for Testing and Materials (ASTM), Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International.

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JAN 2019
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